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EXAMINER

SAYALA, CHHAYA D

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1781

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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

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Continuation of 11:

A. The amendments proposed include a number of issues under 35 USC 112, second paragraph and therefore, will not be entered. For instance, claim 1 is a closed claim and yet claims 5, 13 and 14 admit further elements by the "further" language. In claim 17, is the moisture content that is "conditioned" referring to the moisture at claim 1? This is not defined. Claim 19 in reciting the term "obtainable" and depending from a closed claim renders the claims 19-20 indefinite. Claims 21-22 are indefinite by adding elements to claim 1. Claim 14 is repetitive and does not further limit claim 1.

B. Claims 19-22 are written in a product-by-process format and as such, it is the novelty of the instantly claimed product that needs to be established and not that of the recited process steps. *In re Brown*, 173 USPQ 685 (CCPA 1972); *In re Wertheim*, 191 USPQ (CCPA 1976).

MPEP § 2113 states:

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

>>The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the

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product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979).

There is no evidence that the product can only be defined by the process steps by which the product is made, and further, it is the ingredients that are being limited by the closed claim and not the process steps. There is no evidence either that the manufacturing process steps would impart any distinctive structural characteristics to the final product. For example consider this disclosure in the instant specification @ the bottom of page 8:

In order to prepare a thermoplastic mass of the above described mixture, it is subjected to an extrusion step. During the extrusion, the starch derivative will be gelatinised. It is preferred to use a twin-screw extruder operated at a temperature of from 95 to 180°C, more preferably from 100 to 150°C. As the mixture will undergo a thorough homogenisation during extrusion, it is not of crucial importance that all ingredients of the mixture are mixed so rigorously as to obtain a homogeneous mixture prior to extrusion. During the extrusion, the starch derivative will be converted from an ordered structure into a less ordered, more or less amorphous structure, which yields a thermoplastic, well processable material. During the last phase of extrusion or during storage of the product some crystallinity might be formed.

Although applicant asserts the formation of thermoplastic material is unobvious, it results concomitantly upon extrusion, which is the same step that prior art uses and therefore, the thermoplastic material obtained (from starch, see page 5, lines 15-20) would result as shown by the primary reference. To that extent the process steps are the same.

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C. The claims as amended overlap with the claims of 10/418327, necessitating an evaluation of a provisional obviousness-type double patenting rejection.

D. Claim 1 includes fatty acid salts and "filler" materials that are shown by the specification to include chalk (calcium carbonate) in an amount **0-10 wt%** (see instant specification, page 8, lines 10-15). The terms "filler materials" are not defined in the specification and it is not clear what the metes and bounds are in view of the "consisting of" language. The same holds good for some of the other broad terms. It is not clear what is excluded and what included.

E. A further new search would be required and further reconsideration in view of references such as US patent 5827565 (see specification, page 1, lines 19-22), US patents 6159616, 6672252, 6200616, etc. all starch based chews with fiber and all extruded.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Sayala whose telephone number is (571) 272-1405. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/C. SAYALA/

Primary Examiner, Art Unit 1781